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Nanotechnology: Using Co-Regulation to Bring Regulation of Modern Technologies into the 21st Century

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NANOTECHNOLOGY: USING CO-REGULATION TO BRING REGULATION OF MODERN TECHNOLOGIES INTO THE 21ST CENTURY

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INTRODUCTION

With the emergence of many cutting-edge technologies, we are often promised radical and unsubstantiated benefits. These benefits may include anything from sunscreens with smoother application to innovative methods for delivering medications throughout the body.[1] With nanotechnology, a wide range of common products have been improved in function, cost effectiveness, or both.[2] Nanotechnology is currently used in products Americans use daily: food, appliances, sunscreen, medication, clothing, and cosmetics. This present application of nanotechnology to enhance our everyday lives shows just how much promise nanotechnology holds for the future.

Nevertheless, nanotechnology may also present new risks. Scientists are not sure whether nanotechnology poses any serious health hazards to humans or the environment. Considering our wide exposure to nanotechnology, it is critical that we identify potential risks and impose regulations that strike a balance between accessing the benefits of nanotechnology and limiting the foreseeable harm to the environment and public health.

Nanotechnology is the manipulation of matter on an atomic scale to create tiny, functional structures.[3] These structures are incredibly small: one nanometer is precisely one-billionth of a meter.[4] Nanotechnology is defined as the production of materials that are between one and one-hundred nanometers in size.[5] Although they cannot be seen with the naked eye, these microscopic structures called "nanoparticles" have been proven to benefit humans in a variety of ways. For example, they can lead to new medical treatments.[6] They also can be used to develop

1. *Some Examples of How Nanotechnology Impacts Our Lives Now*, NANOTECHNOLOGY NOW, http://www.nanotech-now.com/current-uses.htm (last updated May 22, 2012, 9:56 PM); *Researchers Create DNA Buckyballs for Drug Delivery*, PHYSORG (Aug. 29, 2005), http://www.physorg.com/news6066.html

2. NANOTECHNOLOGY NOW, *supra* note 1.

3. *Extramural Research: Nanotechnology*, EPA, http://epa.gov/ncer/nano/questions/index.html (last updated Mar. 22, 2011).

4. David Bradley, *Measuring Up Size Comparisons*, SCIENCEBASE (June 7, 2007, 4:00 PM), http://www.sciencebase.com/science-blog/measuring-up-size-comparisons.html.

5. MARK RATNER & DANIEL RATNER, NANOTECHNOLOGY: A GENTLE INTRODUCTION TO THE NEXT BIG IDEA 7 (Michelle Vincenti ed., 2003); *see* A. Elder et al., *Human Health Risks of Engineered Nanomaterials*, *in* NANOMATERIALS: RISKS AND BENEFITS 3, 5 (Igor Linkov & Jeffery Steevens eds., 2009).

6. *See, e.g.*, Elizabeth Bahm, *Fullerene Finding Shows Possibilities and Dangers of Nanotechnology (*Apr. 8, 2010), http://news.medill.northwestern.edu/chicago/news.aspx?id=162744.

building materials with a very high strength-to-weight ratio.[7] Sunscreen and cosmetics that make use of nanoparticles apply more smoothly and evenly to human skin.[8] Other examples of products that utilize nanoparticles include stain-resistant clothing, lightweight golf clubs, bicycles, car bumpers, antimicrobial wound dressings, and synthetic bones.[9]

While there are many benefits presented by nanotechnology, there are also potential risks. Studies have indicated that nanoparticles called carbon nanotubes act like asbestos within the human body.[10] Cells that are exposed to nanostructures called "buckyballs"[11] have been shown to undergo slowed or even halted cell division.[12] In general, the small size and high surface-area-to-volume ratio of nanoparticles indicates a higher potential for toxicity.[13]

The application of nanotechnology to drug development has aided the treatment of common life-threatening diseases while concurrently posing toxic side effects.[14] For example, carbon nanotubes[15] may be used to enhance cancer treatments, but there is also an indication that the nanotubes themselves might ironically have a carcinogenic effect on the human body.[16] Certain nanoparticles can be used to enhance water filtration systems, but there are concerns that the production of nanoscale products may lead to new types of water pollution.[17] Common

7. Min-Feng Yu et al., *Strength and Breaking Mechanism of Multiwalled Carbon Nanotubes Under Tensile Load*, 287 SCIENCE 637, 637 (2000).

8. NANOTECHNOLOGY NOW, *supra* note 1.

9. *Id.*; Vivian S.W. Chan, *Nanomedicine: An Unresolved Regulatory Issue*, 46 REG. TOXICOLOGY & PHARMACOLOGY 218, 220 (2006).

10. *See infra* Part I.C.

11. *See infra* Part I.C.

12. *See infra* Part I.C.

13. GEORGIA MILLER, NANOMATERIALS, SUNSCREENS AND COSMETICS: SMALL INGREDIENTS BIG RISKS 6 (May 2006), *available at* http://nano.foe.org.au/sites/default/files/FoEA%20nano%20cosmetics%20report%202MB.pdf. ("There is a general relationship between particle size and toxicity; the smaller a particle, the greater its surface area to volume ratio, and the more likely it is to prove toxic.").

14. *Nanotubes and their Applications*, UNDERSTANDINGNANO.COM, http://www.understandingnano.com/nanotubes-carbon.html (last visited May 12, 2013).

15. Carbon nanotubes are a tube-like nanoscale structure made from carbon that are very strong and very lightweight and have been found to have many uses, from medical treatments to enhancing building materials. *See id.*

16. *See infra* Part I.C.

17. David Grimshaw, *Nanotechnology for Clean Water: Facts and Figures*, SCIDEV.NET (May 6, 2009), http://www.scidev.net/en/agriculture-and-

to these examples is the difficulty in determining whether the benefits of nanotechnology will outweigh the risks.

One place to turn for answers is the regulatory agency tasked with investigating the risks posed by nanotechnology. The Environmental Protection Agency (EPA) has the regulatory authority to assess the environmental and public health risks associated with nanotechnology, and to prescribe regulations as needed to prevent or reduce those risks.[18] Unfortunately, authority to assess those risks does not mean the EPA has adequate tools to do so.[19] Nanotechnology is becoming ubiquitous as the industry continues to expand, and new products are being created every day.[20] The need for thorough risk assessment, followed by appropriate risk management, is becoming more important as potential environmental and public exposure to nanoparticles is becoming more common.[21]

Nanotechnology is not categorically dangerous.[22] The current danger is that it is *unknown* whether nanoparticles present any risks to the environment and public health. As more common household products are created or enhanced with nanoparticles, public exposure to nanotechnology is increasing rapidly.[23] This increasing public exposure indicates an urgent need for risk assessment. And as exposure increases, it becomes more important that the EPA be able to determine what risks will accompany that exposure, if any, so that it can properly balance the risks against the benefits and promulgate the most effective rules.

Generally speaking, the EPA is familiar with assessing risks and regulating new products. The EPA has authority through the Toxic Substances Control Act (TSCA) to regulate chemical manufacturing.[24] TSCA requires manufacturers to inform the EPA of the potential risks associated with a new product, or new uses for an existing product, before production begins.[25] This gives the EPA an opportunity to prohibit or limit the manufacturing of that substance.[26] While this seems

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environment/land-water-pollution/features/nanotechnology-for-clean-water-facts-and-figures.html.

18. *See* 15 U.S.C. § 2601 (2011).

19. J. CLARENCE DAVIES, EPA AND NANOTECHNOLOGY: OVERSIGHT FOR THE 21ST CENTURY 24 (2007), *available at* http://www.nanotechproject.org/process/assets/files/2698/197_nanoepa_pen9.pdf [hereinafter DAVIES 1].

20. *See id.* at 13.

21. *Id.*

22. *Id.* at 13–14.

23. *Id.*

24. 15 U.S.C. § 2601 (2011).

25. *Id.* § 2601(b)(1).

26. *Id.* § 2601(b)(2).

to suggest that the EPA is well-equipped to manage the potential risks of products containing nanoparticles, some say that TSCA is outdated and that it will be difficult to use this older statute to regulate modern technology.[27]

Part I of this Note provides background on nanotechnology, including what it is, how it can be useful, and risks it may present. Part II discusses the potential use of TSCA to assess the risks associated with new technologies and the challenges that may arise in trying to apply TSCA to nanotechnology.[28] Part III proposes alternatives to using current EPA regulations to regulate nanotechnology. These alternatives include self-regulation, agency regulation through a newly proposed agency, and a way to combine the benefits of these proposals while eliminating the weaknesses through the use of co-regulation and the creation of a Nanotech Division within each key agency associated with nanotechnology.

I. WHAT IS NANOTECHNOLOGY?

Nanotechnology is the creation of functional structures with at least one dimension that measures between one and one hundred nanometers.[29] To illustrate how small this is, a human hair is approximately 100,000 nanometers wide.[30] Comparing a nanometer to a meter is equivalent to comparing the size of a marble to the size of the Earth.[31] When an element or molecule is manufactured on the nanoscale, it may have different physical and chemical properties than those found in the same element or molecule manufactured on a large scale.[32] If a one-inch cube of gold is cut into four equal pieces, each of those pieces will retain the physical and chemical properties of the original cube of gold—including melting point, boiling point, color, etc. This will remain true as you continue cutting the gold into smaller and smaller pieces, even when the pieces are too small to be seen with the naked eye. But once those pieces

27. *See* J. CLARENCE DAVIES, OVERSIGHT OF NEXT GENERATION NANOTECHNOLOGY 23-24 (2009), *available at* http://www.nanotechproject.org/process/assets/files/7316/pen-18.pdf [hereinafter DAVIES 2].

28. It is important to keep in mind that while the EPA is involved with a wide range of environmental concerns, from product development to waste disposal, the scope of this Note is focused on regulating nanotechnology at the earliest stages of development, production, manufacturing and marketing to consumers.

29. Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622, 622 (2006).

30. *How Big is a Nanometer?!*, NANOSCIENCE KITS (Jan. 20, 2010, 2:02 PM), http://www.nanosciencekits.org/how-big-is-a-nanometer.

31. Christopher J. Chetsanga, Professor, Univ. of Zimbabwe, Presentation at Breakout Session on Nanotechnology in Health Sciences (Nov. 4–6, 2009) (on file with author).

32. *See* RATNER & RATNER, *supra* note 5, at 12.

are so small that they enter the nanoscale, those physical and chemical properties may change.[33]

The manufacture of nanoscale materials, or nanofabrication, can occur in one of two ways. Top-down nanofabrication is when a large item is cut down to the nanoscale.[34] Bottom-up nanofabrication is when individual atoms are assembled to create a nanostructure.[35] Both types of nanofabrication produce nanoparticles exhibiting new chemical or physical properties or both. This can lead to a variety of new products and enhancement of existing products. One element in particular, carbon, has been found to be very useful on the nanoscale. Carbon nanotubes are known for being extremely lightweight and extremely strong, having the highest tensile strength[36] of any material tested.[37]

A. The Unsuspecting Consumer of Nanomaterials

Most consumers are unaware or unconcerned that many common products they use contain nanoscale materials, including food, sunscreen, hair straighteners, clothing, computer hardware, bicycles, wound dressings, air sanitizing spray, health supplements, bricks, toothpaste, baby products, and automotive lubricants.[38] Non-profit consumer safety groups have voiced concerns regarding consumers being unknowingly exposed to nanomaterials through the application of sunscreen or the foods they eat.[39] While these non-profit consumer safety groups have begun to take action, surveys have shown that the public may not be concerned with the risks associated with nanotechnology.[40] A 2011 survey showed that consumers ranked the risks associated with nanotechnology fairly low when compared to other health risks.[41]

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33. *Id.*

34. *Id.*

35. *Id.*

36. Tensile strength is the "force required to pull something such as rope, wire, or a structural beam to the point where it breaks." *Science Reference: Tensile Strength*, SCIENCE DAILY, http://www.sciencedaily.com/articles/t/tensile_strength.htm (last visited May 11, 2013).

37. Yu et al., *supra* note 7, at 637.

38. *All Products*, PROJECT ON EMERGING NANOTECHNOLOGIES http://www.nanotechproject.org/inventories/consumer/browse/products/ (last visited May 11, 2013) (providing a list of consumer products containing nanoscale materials).

39. *Consumer Safety Groups File First Lawsuit on Risks of Nanotechnology*, NANOTECHNOLOGY NOW, http://www.nanotech-now.com/news.cgi? story_id =44147 (Dec. 21, 2011).

40. John Timmer, *US Public Fears a Bad Sunburn More than Nanotech*, ARS TECHNICA (Apr. 15, 2011, 12:39 PM), http://arstechnica.com/science/2011/04/us-public-fears-a-bad-sunburn-more-than-nanotech.

41. *Id.*

While it is understandable that consumers expect commonly used products to be safe for everyday use, the demand for complete safety may be unreasonable. There are many common products that do not utilize nanotechnology that will never be completely risk-free, including cars, over-the-counter pain medications, and steak knives. There are risks involved in the use of these products, but the benefits of proper use outweigh those risks. The same may be true for nanotechnology.

Some nanotechnology products are less common or do not involve regular consumer exposure. For example, nanomedicine is a quickly growing field of study.[42] Nanomedicine is the use of nanotechnology for medical purposes, including the enhancement of pharmaceuticals and medical devices.[43] Studies have suggested that nanotechnology could play an important role in treating cancer.[44] There is no doubt that many people would be in favor of technological advances that have the potential to save lives or enhance quality of life. There may be less concern over the potential risks of nanotechnology when those who are in need of medical treatments are informed of the benefits.

B. Nanotoxicology: The Toxic Effects of Nanotechnology

Nanotoxicology is an emerging area of study that explores the effects of nanoparticles within the body.[45] Nanoparticles can enter the human body through several types of exposure, including ingestion, inhalation, injection, and skin absorption.[46] Exposure to nanotechnology occurs even without technological advances because nanoparticles exist naturally in the environment.[47] While humans have always been exposed to nanoparticles,

42. *See What is Nanomedicine,* NANOMEDICINE CENTER, http://www.nanomedicinecenter.com/what-is-nanomedicine (last visited May 11, 2013).

43. *Id.*

44. *Researchers Effectively Treat Tumors with Use of Nanotubes*, WAKE FOREST BAPTIST MEDICAL CENTER, http://www.wakehealth.edu/News-Releases/2009/Researchers_Effectively_Treat_Tumors_with_Use_of_Nanotubes.htm (last updated Aug. 13, 2009) [hereinafter WAKE FOREST]; *Researchers Use Nanotubes to Treat Tumors*, RADIOLOGY TODAY, http://www.radiologytoday.net/news/082509_news.shtml (last visited May 16, 2013).

45. *See* Günter Oberdörster et al., *Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, 113 ENVTL. HEALTH PERSP. 823, 823 (2005); *The Dose Makes the Poison*, 6 NATURE NANOTECHNOLOGY 329, 329 (2011). Nanotoxicology involves researching the ways that nanoscale particles can react differently within the body than particles of the same material in a larger size. The toxicity of nanomaterials can be "unexpected and unusual" and the interactions between nanoparticles can be dynamic, making it very challenging to determine how nanoparticles will react within the human body. *Id.*

46. Oberdörster, *supra* note 45, at 823.

47. *Id.*

nanotoxicology is important now because human exposure has "increased dramatically" due to the use of nanotechnology in a variety of products.[48] This has made it essential that researchers go beyond simply studying the toxicology of nanoparticles within the body in general and begin studying the toxicology of larger quantities of nanoparticles within the body.

Research has shown that large-scale materials that are harmless can become more toxic when they are manufactured down to the nanoscale.[49] With relatively little knowledge of how nanoparticles will react within the human body, it is difficult to determine when risks are posed to human health or how severe those risks may be.[50] As discussed below, some studies have indicated that nanostructures called carbon nanotubes may act similarly to asbestos within the body, which could lead to life-threatening diseases like cancer.[51] Due to our current knowledge of asbestos toxicology, some scientists have chosen to focus on the toxicity of long-term exposure to nanoparticles compared to the toxicity of short-term exposure.[52] To date, there have not been any reports of deaths from short-term exposure to nanoparticles, but the story of asbestos began the same way. It was only after long-term exposure that people started getting sick and dying from asbestosis.[53]

One general concern is that nanoparticles tend to aggregate within the body, creating an increased volume of nanoparticles with each additional exposure.[54] There also appears to be a "natural passageway" for nanoparticles to delve into and around the body through the membranes that separate bodily organs.[55] This natural passageway gives nanoparticles a high level of mobility within the body.[56] Increased mobility of nanoparticles within the body means that inhaled particles will not be restricted to the lungs; similarly, ingested particles will not be restricted to the gastrointestinal tract.[57] While this should not be

48. *Id.*

49. Chan, *supra* note 9, at 220.

50. *See id.* at 221.

51. *See infra* Part I.C; Atsuya Takagi et al., *Induction of Mesothelioma in P53+/- Mouse by Intraperitoneal Application of Multi-walled Carbon Nanotube*, 33 J. TOXICOLOGICAL SCI. 105, 105–06 (2008).

52. Chan, *supra* note 9, at 221.

53. *Id.*; *Asbestos Exposure and Cancer Risk*, NAT'L CANCER INST., http://www.cancer.gov/cancertopics/factsheet/Risk/asbestos (last updated May 1, 2009).

54. Chan, *supra* note 9, at 221.

55. *Id.*

56. *Id.*

57. *See* Wim H. De Jong & Paul J.A. Borm, *Drug Delivery and Nanoparticles: Applications and Hazards*, 3 INT. J. NANOMEDICINE 133, 133 (2008); Chan,

medically alarming in and of itself, it does hint at the potential for any harm from nanoparticles to be widespread throughout the body.

Other concerns arise from findings that show that certain nanoparticles may be transmitted to a fetus through the mother's placenta, although it is unknown whether this could have a negative impact on fetal development or the future health of the child.[58] If exposure to nanoparticles is ever confirmed to cause health risks in general, those risks would be magnified by the fact that any pregnant woman exposed to nanoparticles will be exposing her fetus as well. This could include exposure that occurs during the pregnancy and exposure that occurred before the pregnancy began, because nanoparticles can accumulate and remain within the body long after exposure.[59]

C. Studies Reporting the Specific Dangers of Nanotechnology

According to some commentators, the uncertainty of risks posed by nanotechnology is particularly worrisome. While the actual risks of nanotechnology may remain unknown, the many routes through which nanoparticles may enter the body[60] suggest that simply being near nanoparticles puts people at risk of having nanoparticles enter their body. This can vary based on the type of product to which one is being exposed. For example, rubbing sunscreen on your skin will more likely lead to absorption than simply touching a bicycle because sunscreen is designed to be absorbed into the skin. Nanoparticles being injected as medication or consumed as food will have a direct entrance into the body. Because nanoparticles have many routes of exposure, scientists must determine what effects those nanoparticles will have once inside

supra note 9, at 221. The ability of nanoparticles to travel easily through barriers between organs introduces both a risk and a benefit. There may be instances where nanoparticles can cause harm by being able to travel freely throughout the body, but there may also be times when the ability of nanoparticles to travel through organ barriers is a useful for drug delivery. *Id.*

58. Chan, *supra* note 9, at 221; Jeffrey A. Keelan, *Nanoparticles Versus the Placenta*, 6 NATURE NANOTECHNOLOGY 263, 263 (2011) (noting that damage to the placenta and fetus were caused by exposing mice to smaller nanoparticles, while mice exposed to larger nanoparticles showed no signs of damage to fetus or placenta); *see generally* Peter Wick et al., *Barrier Capacity of Human Placenta for Nanosized Materials*, 118 ENVTL. HEALTH PERSPS. 432 (2010) (detailing a study that showed testing on human placentas showed nanoparticles were able to cross the placental barrier).

59. Y. Song et al., *Exposure to Nanoparticles is Related to Pleural Effusion, Pulmonary Fibrosis and Granuloma*, 34 EUR. RESPIRATORY J. 559, 559 (2009); *see Poison*, *supra* note 45, at 329.

60. *See* Oberdörster et al., *supra* note 45, at 823.

the body. Several studies on the effects of nanoparticles in the body have been conducted, and the results have been mixed.[61]

One study, known as the Takagi study, suggests that carbon nanotubes present serious enough risks to be labeled "the next asbestos."[62] This label should not be taken lightly, as the long-term health effects of asbestos became a major concern after years of acute asbestos exposure led to mesothelioma in a large number of people.[63] In the Takagi study, mice exhibited symptoms similar to mesothelioma after being injected with multi-walled carbon nanotubes (MWCNTs).[64] The Takagi study was later "criticized for the use of extremely high doses" of MWCNTs;[65] another researcher indicated that the doses were "highly unrealistic."[66]

A second study, known as the Poland study, was conducted to further investigate the "asbestos-like pathogenicity" of MWCNTs.[67] The Poland study led to results similar to those in the Takagi study, including the formation of granulomas and inflammation in mice, and the researchers concluded that the size and shape of the injected MWCNTs was a factor that contributed to the negative health effects.[68] While all MWCNTs are nanoparticles, their exact size and shape can vary.[69]

61. *See id.*; Takagi et al., *supra* note 51; Craig A. Poland et al., *Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-Like Pathology in a Pilot Study*, 3 NATURE NANOTECHNOLOGY 423, 423 (2008).

62. *See* Takagi et al., *supra* note 51.

63. Mesothelioma is a rare lung cancer that is caused by exposure to asbestos. Asbestos fibers can lodge into a protective membrane around the lungs called the mesothelial lining. Tumors can form where the asbestos fibers have lodged in the mesothelial lining. Researchers have hypothesized how this leads to cancer. One idea is that the asbestos fibers cause irritation to the lining, which can then lead to "irreversible scarring, cellular damage and cancer." Another possibility is that the asbestos fibers interrupt cellular division, causing genetic changes that lead to cancer. A final theory is that the asbestos releases free radicals, which then damage the DNA and cause healthy cells to become cancerous. *Mesothelioma Causes,* MESOTHELIOMA CTR., http://www.asbestos.com/mesothelioma/causes.php (last modified Feb. 18, 2013).

64. Takagi et al., *supra* note 51, at 105. MWCNTs are a type of nanoparticle that has been researched for use in medical devices, as well as for many unrelated uses, but have been shown to possibly have negative health effects similar to mesothelioma. *See id.*

65. Gaku Ichihara et al., *Letter to the Editor*, 33 J. TOXICOLOGICAL SCI. 381, 381 (2008); Andrew D. Maynard et al., *The New Toxicology of Sophisticated Materials: Nanotoxicology and Beyond*, 120(S1) TOXICOLOGICAL SCI. S109, S116 (2010).

66. Ichihara et al., *supra* note 65, at 381.

67. Poland et al., *supra* note 61, at 423

68. *Id.*

69. *Id.*

Researchers found that the longer, thinner MWCNTs caused more granulomas and inflammation than the shorter, thicker ones.[70] Although researchers are not entirely sure why exposure to asbestos particles causes lung cancer, most hypotheses indicate that it is the size and shape of the asbestos particles, not the chemical make-up, that leads to lung cancer after asbestos exposure.[71] The Poland study has been criticized for falsely concluding that the health effects caused by MWCNTs injected into mice stomachs are an accurate representation of the health effects that humans would experience after inhaling MWCNTs.[72]

In another study, done at Los Alamos National Laboratory (the Los Alamos study), researchers studied fullerenes, also known as "buckyballs," which are cage-like nanostructures made of carbon and shaped like soccer balls.[73] Researchers have suggested that buckyballs would make excellent drug delivery devices.[74] In the Los Alamos study, researchers studied plain buckyballs, as well as two modified versions known as "tris" and "hexa."[75] While the plain and hexa buckyballs showed no damage to cells, the tris configuration had a toxic reaction within human tissue.[76] The researchers noted that the presence of these buckyballs induced "cell cycle arrest and premature senescence in human skin cells." [77] In other words, the cells stopped growing, dividing, and dying, as if their lifecycles simply ended.[78] This study demonstrated

70. *Id.*

71. *See* MESOTHELIOMA CTR., *supra* note 63.

72. John C. Monica, Jr. & John C. Monica, *A Nano-Mesothelioma False Alarm*, 5 NANOTECHNOLOGY L. & BUS. 319, 319 (2008).

73. Jun Gao et al., *Fullerene Derivatives Induce Premature Senescence: A New Toxicity Paradigm or Novel Biomedical Applications*, 244 TOXICOLOGY & APPLIED PHARMACOLOGY 130, 130 (2010); Bahm, *supra* note 6.

74. Bahm, *supra* note 6; *Researchers Create DNA Buckyballs for Drug Delivery*, PHYSORG (Aug. 29, 2005), http://www.physorg.com/news6066.html; *see* Darshana Nagda et al., *Bucky Balls: A Novel Drug Delivery System*, 2 J. CHEMICAL & PHARMACEUTICAL RES. 240, 243-44 (2010).

75. Gao et al., *supra* note 73, at 131. "Tris" and "hexa" refer to the number of branches that come off of the buckyball structure. A "plain" buckyball has no branches, a tris buckyball has three branches, and a hexa buckyball has six branches. The various configurations can lead to different uses for the buckyballs, as well as different risks. *Carbon Nanostructures*, LOS ALAMOS NATIONAL LIBRARY, http://tri-lab.lanl.gov/index.php/scientific-discovery/62-carbon-nanostructures (last visited May 12, 2013).

76. Gao et al., *supra* note 73, at 131.

77. *Id.*

78. *Carbon Nanostructures: Elixir or Poison?*, SCIENCE DAILY (Apr. 1, 2010), http://www.sciencedaily.com/releases/2010/03/100331151146.htm.

that a tiny change in nanostructures can be the "difference between treatment and toxicity."[79]

The three studies above highlight the importance of assessing the risks of nanotechnology and regulating those risks appropriately. If even small changes in the nanostructure can be the difference between something beneficial and something dangerous, regulators will want to ensure that research is conducted to clarify exactly what risks are present so they can regulate accordingly. There may also be a chance that a nanomaterial deemed safe could accidentally be manufactured incorrectly due to human error or another type of malfunction. For example, if a buckyball structure is determined to be safe for use as a drug delivery method, regulators should require that manufacturing of that product follow strict inspection and quality guidelines to ensure that only safe configurations of buckyballs are produced and marketed.

D. The Benefits of Nanotechnology

Nanotechnology serves a variety of useful purposes. In some instances, entirely new products have been created using nanotechnology. In other cases, nanotechnology has improved products that already exist by increasing their function, cost-effectiveness, or both.

While there are a wide variety of uses for nanotechnology, carbon nanotubes in particular offer one of the most intriguing, and perhaps desired uses: enhanced cancer treatments. A collaborative research study by Wake Forest University School of Medicine, the Wake Forest University Center for Nanotechnology and Molecular Materials, Rice University, and Virginia Polytechnic Institute and State University showed that when MWCNTs are inserted into tumors and then exposed to laser-generated near-infrared radiation there is a high rate of tumor elimination.[80]

During the study, researchers injected MWCNTs into kidney tumors in mice. Some mice were injected with more MWCNTs than others, and some were not injected at all.[81] Some were exposed to the radiation and some were not.[82] Mice that received no treatment died within thirty days of the beginning of the study.[83] Mice that were injected with the MWCNTs but not exposed to the radiation and mice that were exposed to the radiation but not injected with the MWCNTs also died within about thirty days.[84] The mice that received the injections of MWCNTs followed by thirty seconds of exposure to the radiation lived much longer

79. Bahm, *supra* note 6.

80. *See* WAKE FOREST, *supra* note 44; RADIOLOGY TODAY, *supra* note 44.

81. WAKE FOREST, *supra* note 44.

82. *Id.*

83. *Id.*

84. *Id.*

than those that did not receive both treatments.[85] The study also showed that the mice that were given higher quantities of MWCNTs lived longer than those that were given smaller quantities.[86] This same study is now being conducted with breast cancer cells in hopes that the results will be similar.[87] If nanotechnology can be used to enhance high-priority medical treatments such as those for cancer, then advancement of that technology is likely to be very desirable.

Nanotechnology offers benefits for the industrial and energy sectors. Nanoscale coatings can be used for weatherproofing, increasing durability, and cleaning.[88] Nanotechnology can be used to enhance operations of our current energy sources or to help the United States transition to "cleaner" sources of energy.[89] Nanoscale substances can be used to create coatings that prevent corrosion and withstand high heat, enhancing the durability of the infrastructure of nuclear power plants.[90] Nanotechnology can also be used in the production of photovoltaic cells used to harness solar power and to improve turbines used to harness wind energy.[91] In addition to these large-scale benefits, nanotechnology can also be used to enhance smaller-scale products like sunscreen and cosmetics in similar ways.[92]

II. BALANCING THE RISKS AND BENEFITS OF NANOTECHNOLOGY

As discussed above, while there are many potentially beneficial uses for nanotechnology, these benefits are often associated with new risks.[93] A principal consideration when regulating nanotechnology will be balancing the benefits and risks.

Nanotechnology has emerged in the United States during a tumultuous political climate. The United States has recently faced a recession

85. *Id.*

86. *Id.*

87. *See* Press Release, Wake Forest Baptist Med. Ctr, Nanotube Therapy Takes Aim at Breast Cancer Stem Cells (Feb. 9, 2012), *available at* http://www.wakehealth.edu/News-Releases/2012/Nanotube_Therapy_Takes_Aim_at_Breast_Cancer_Stem_Cells.htm.

88. NANOTECHNOLOGY NOW, *supra* note 1.

89. *The 'Power' of Nanotechnology*, NANOTECHNOLOGY NOW (July 13, 2007), http://www.nanotech-now.com/columns/?article=078.

90. *Id.*

91. *Id.*; Sandra Knisely, *Carbon Nanotubes May Cheaply Harvest Sunlight*, PHYSORG (Oct. 19, 2009), http://www.physorg.com/news175182633.html.

92. NANOTECHNOLOGY NOW, *supra* note 1.

93. *See supra* Part I.

from which it is still recovering.[94] Because of the recession, the public has placed pressure on the President and other politicians to avoid heavy regulatory burdens on industrial manufacturers.[95] Regulating nanotechnology too heavily may raise costs for consumers and inhibit technological advances, while failing to regulate at all could put public health at risk.

One avenue for regulating environmental health and safety (EHS) risks associated with nanotechnology is the EPA's Toxic Substances Control Act (TSCA).[96] TSCA is a "risk-benefit balancing statute" meant to balance the risks posed by a chemical or substance being regulated against the economic consequences of regulation.[97] The EPA collects information through TSCA about new substances to be manufactured, and uses that information to decide when to intervene by limiting or banning production.[98] TSCA requires the EPA to make findings with regard to the EHS of new products as well as the benefits of those products, the availability of alternatives, and the "reasonably ascertainable economic consequences" of regulating those products.[99] TSCA also requires the EPA to regulate products as necessary to protect against potential risks, but only by imposing the *least burdensome requirements*.[100]

A. The Toxic Substances Control Act

TSCA is described as a "front-loaded" statute because it is meant to assess the environmental risks associated with a material before manufacturing and marketing occur.[101] Through TSCA, the EPA

94. *See* Chris Isidore, *It's Official: Recession Since Dec. '07*, CNN MONEY, http://money.cnn.com/2008/12/01/news/economy/recession/index.htm (last updated Dec. 1, 2008, 5:40 PM EST).

95. Bill Vlasic, *U.S. Sets Higher Fuel Efficiency Standards*, N.Y. TIMES, Aug. 29, 2012, at B1; *A Look Ahead to EPA Regulations for 2013: Numerous Obama EPA Rules Placed On Hold Until After the Election Spell Doom for Jobs and Economic Growth*, CNS NEWS, http://cnsnews.com/sites/default/files/ documents/A_Look_Ahead_to_ EPA_Regulations_for_2013.pdf; *see* Larry Bell, *EPA's Insanely Ambitious Agenda if Obama is Reelected*, FORBES (Nov. 4, 2012, 12:18 PM), http://www.forbes.com/sites/larrybell/2012/11/04/epas-insanely-ambitious-agenda-if-obama-is-reelected.

96. J. CLARENCE DAVIES, MANAGING THE EFFECTS OF NANOTECHNOLOGY 10–12 (2006), *available at* http://www.nanotechproject.org/process/assets/files/2708/30_pen2_mngeffects.pdf [hereinafter DAVIES 3].

97. ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE, AND POLICY 245–47 (6th ed. 2009).

98. *Id.* at 247.

99. *Id.*; Toxic Substances Control Act (TSCA), 15 U.S.C. § 2605(c)(1) (2006).

100. 15 U.S.C. § 2605(a).

101. NANOTECHNOLOGY: ENVIRONMENTAL LAW, POLICY, AND BUSINESS CONSIDERATIONS 13 (Lynn L. Bergeson ed., 2010) [hereinafter Bergeson].

regulates substances in three categories: (1) new substances that are not yet on the TSCA inventory, (2) substances that have already been assessed and placed on the TSCA inventory based on their current use, and (3) substances that are on the TSCA inventory but that are being used in a new way that may change the associated risks.[102] One roadblock in regulating nanotechnology through TSCA is determining how to categorize nanotech products. Classifying a nanotech material as a new substance, a substance already on the TSCA inventory, or a new use for a TSCA inventory substance will affect how rigorously it is assessed before being approved for manufacturing.[103] In many cases, manufacturers may be confused as to what they need to file with the EPA as they may be unsure of their product's classification.

1. The TSCA Process

Under TSCA Section 8, the EPA keeps an inventory of all existing chemical substances that are manufactured or processed in the United States.[104] TSCA Section 6 gives the EPA authority to prohibit or limit the manufacturing, processing or distribution of substances or mixtures containing substances that are on the TSCA inventory.[105] "New chemical substances" are placed on the TSCA inventory through the pre-manufacture notice process.[106] Manufacturers are required to submit information to the EPA about new chemical substances at least ninety days before production begins.[107] The required documentation includes basic chemical data as well as any available information regarding health risks.[108] The EPA uses the pre-manufacture notice to determine whether manufacturing of the substance should be allowed without restrictions, allowed with some limitations, or banned altogether.[109] A decision to limit or ban production will be based on whether there is a reasonable basis to conclude that the manufacturing of that substance poses an unreasonable risk to human health or the environment.[110] Once a substance is placed on the TSCA inventory, all subsequent manufactur-

102. 15 U.S.C. § 2604(a) (2006).

103. *Id.*

104. *Id.*

105. 15 U.S.C. § 2605(a) (2006).

106. *Id.* § 2604(a).

107. *Id.* § 2604(a)(1).

108. *Id.* § 2604(b)(2)(B)(i).

109. *Id.* § 2605(a).

110. *Id.*

ers who plan to use that substance in the same way are bound by the limitations set by the EPA.[111]

The EPA also has the authority to restrict or ban the manufacturing of TSCA inventory substances that are being used in a way that is considered a "significant new use."[112] Using the same pre-manufacture notice process as it does for new chemical substances, the EPA requires documentation from the manufacturer explaining the chemical, the intended use of the chemical, and any known risks.[113] If the EPA determines that the product is going to be put to a "significant new use," it will set a significant new use rule (SNUR) for that substance.[114] The SNUR sets out any limitations the EPA deems necessary for the safe production of that substance for its new use. Anyone who intends to manufacture it for purposes of that significant new use will be bound by the SNUR promulgated by the EPA.[115]

2. Limitations on TSCA Authority

While the basic TSCA framework appears to give the EPA authority to decide which products should have limitations and which products should be banned, this authority is not without limits.[116] As shown above, the EPA must balance the potential risks and benefits of a product while also considering the availability of substitutes and the economic consequences of regulating the product.[117]

In 1989, the EPA issued a final rule under TSCA prohibiting the manufacture and use of asbestos.[118] The EPA determined, after ten years of research and consideration, that asbestos presented an unreasonable risk to human health, and that the best way to reduce that risk was to ban production of asbestos.[119] The asbestos industry quickly challenged this rule in *Corrosion Proof Fittings v. EPA*.[120] In *Corrosion*, the Fifth Circuit Court of Appeals struck down the EPA's ban as being too burdensome for a product for which there were no substitutes presently available and because the cost of banning asbestos would be excessive

111. *New Chemical Consent Orders and Significant New Use Rules (SNURs)*, EPA, http://www.epa.gov/oppt/newchems/pubs/cnosnurs.htm (last updated Sept. 28, 2012).

112. 15 U.S.C. § 2604(a) (2006).

113. EPA, *supra* note 111.

114. *Id.*

115. *Id.*

116. PERCIVAL ET AL., *supra* note 97, at 247–59.

117. *Id.* at 247.

118. 54 Fed. Reg. 29,460, 29,460 (July 12, 1989).

119. *Id.*

120. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1207 (5th Cir. 1991).

when compared to the number of lives that would be saved by the ban.[121] The *Corrosion* Court's holding shows that the EPA's authority to limit or ban production of a material is not unlimited and that before the EPA can ban production of a material it must provide *substantial evidence* that the benefits of the regulation bear a reasonable relationship to the costs of the regulation.[122]

B. A Square Peg in a Round Hole: Applying TSCA to Nanotechnology

The EPA may have authority to regulate nanotechnology through TSCA, but that does not mean that TSCA is an adequate method for protecting against EHS risks.[123] Based on the processes and limitations of TSCA, the EPA will face several challenges in attempting to regulate nanotechnology.[124] First, many nanomaterials are essentially smaller versions of existing materials. When this occurs, the EPA must decide whether to treat the nanoscale version the same as they treat the large-scale version.[125] The initial classification as new, existing, or a significant new use will have a significant impact on whether the product will be regulated at all.[126]

Second, as discussed above, there is still uncertainty as to what risks are associated with nanotechnology.[127] The TSCA process requires that manufacturers supply the EPA with material risk information before manufacturing begins, but TSCA does not require that the manufacturer actually perform an in-depth risk assessment.[128] Instead, manufacturers are only required to submit the material and risk information that is available to them, and the EPA may require testing if it finds that a material may pose an unreasonable risk.[129] There is no incentive for manufacturers to engage in voluntary, in-depth risk assessment because a lack of risk information is construed as a lack of risk.[130] By providing minimal risk information, a manufacturer can be in compliance with TSCA while avoiding limitations on production that may have been imposed if further risk information had been provided.[131]

121. *Id.* at 1229.

122. *Id.* at 1220.

123. *See* DAVIES 1, *supra* note 19, at 24.

124. *Id.* at 22–23; Bergeson, *supra* note 101, at 6-7.

125. *See* DAVIES 1, *supra* note 19, at 22–24; Bergeson, *supra* note 101, at 7.

126. *See* DAVIES 1, *supra* note 19, at 23.

127. *See supra* Parts I.B–C.

128. Toxic Substances Control Act (TSCA), 15 U.S.C. § 2603 (2010).

129. *Id.* § 2603(a)(1)(A)(i).

130. DAVIES 3, *supra* note 96, at 11–12.

131. *See id.*

Finally, once the EPA has weighed the risks and benefits of a nanotech substance, it must regulate using the least burdensome requirements.[132] As we have seen with asbestos, determining the least burdensome requirements can be subjective, and if the EPA's determination does not properly balance risks, benefits, and costs, then the regulation may be overturned if challenged.[133] It is unclear whether TSCA intended the alternatives for limiting material production to be a hierarchy, so without further guidance, the EPA may not have a clear way of measuring whether one alternative is more burdensome than another.[134]

1. Classification Confusion and Proposed Alternatives

The EPA has already taken steps toward determining how it will classify nanomaterials for purposes of TSCA.[135] Because many of those materials have a large-scale version already on the TSCA inventory, it is difficult to determine whether those nanoscale substances should be treated as new substances, substances already on the inventory, or significant new uses of substances already on the inventory.[136] In 2008, the EPA released a document addressing the classification issue.[137] In this paper, the EPA stated that its expectation was that while some nanoscale substances may qualify under TSCA as new chemical substances, not all of them will, and that the EPA would have to follow its historical approach of determining the "inventory status of chemical substances" on a "case-by-case" basis.[138]

TSCA defines a "chemical substance" as "any organic or inorganic substance of a particular molecular identity . . . ."[139] The EPA defines molecular identity as being "based on such structural and compositional features as the types and number of atoms in the molecule, the types and number of chemical bonds, the connectivity of atoms in the molecule, and the spatial arrangement of atoms within the molecule."[140] When two substances have the same molecular identity, the EPA has declined to use particle size to distinguish the substances for purposes of

132. 15 U.S.C. § 2605(a).

133. *See supra* Part II.A.2.

134. *See supra* Part II.A.2.

135. Bergeson, *supra* note 101, at 7-9.

136. EPA, TSCA INVENTORY STATUS OF NANOSCALE SUBSTANCES – GENERAL APPROACH 1-3 (2008), *available at* http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf [hereinafter INVENTORY STATUS].

137. *Id.* at 1.

138. *Id.* at 2.

139. Toxic Substances Control Act (TSCA), 15 U.S.C. § 2602(2)(A) (2010).

140. INVENTORY STATUS, *supra* note 136, at 3.

the TSCA inventory.[141] When both a nanoscale version and a large-scale version of a substance exist, and both versions have matching molecular identities, placing either on the TSCA inventory "will encompass both . . . forms of the substance."[142] It follows that when a large-scale substance is already on the TSCA inventory, any new nanoscale versions of that substance will be considered an existing chemical.[143]

An alternative to this would be to consider a nanoscale version of a large-scale substance to be a significant new use. If considered a significant new use, the nanoscale version of the substance would require a more rigorous assessment than an existing substance, similar to the assessment required for a new substance.[144] This would not overcome the fact that new substance assessments may be insufficient, but it is an alternative to considering the nanoscale substances to be existing chemicals and to require no assessment at all.

The EPA has begun the regulatory process for some types of carbon nanotubes.[145] The EPA's *Inventory Status of Nanoscale Substances* emphasizes the approach the EPA has always used in classifying substances under TSCA—focusing on the molecular identity of the substances.[146] The EPA makes a general statement that "a molecule is the smallest unit of matter that retains all of its chemical properties."[147] This definition illustrates that the EPA's historical methods for determining whether a substance is a "new" or "existing" chemical cannot be so easily applied to nanotechnology, for one of the main traits of nanoscale substances is that they *do not retain the chemical properties of their large-scale counterparts.*[148] The nanoscale version of a substance is no longer the same molecule because it now has different chemical properties than the large-scale version of the same substance and thus may present different risks than the large-scale version.[149]

The EPA, however, does not consider the physical and chemical properties when defining a substance as "new" or "existing."[150] The EPA only considers molecular properties in determining whether two

141. *Id.* at 4.

142. *Id.* at 5.

143. *See id.* at 5; *see also* EPA, MEETING SUMMARY REPORT: MATERIAL CHARACTERIZATION OF NANOSCALE MATERIALS (2007), *available at* http://www.epa.gov/opptintr/nano/mc09072007-mtgsummary.pdf.

144. *See* INVENTORY STATUS, *supra* note 136, at 5–6.

145. 76 Fed. Reg. 26,192 (May 6, 2011).

146. INVENTORY STATUS, *supra* note 136, at 2–3.

147. *Id.* at 3.

148. *See supra* Part I.

149. *See supra* Part I.

150. INVENTORY STATUS, *supra* note 136, at 2–3.

substances are the same.[151] The EPA should consider the fact that two substances may have the same molecular identity but different chemical and physical properties, and those properties should lead to a more stringent method for determining whether a nanoscale substance is the "same" as the large-scale version.

The rationale behind more stringent testing for molecularly similar but physically and chemically different substances applies equally to evaluating locations on a simple road map. Two road maps from different places can appear the same: the roads can have very similar layouts and patterns making the two locations look identical. But if you actually visited those two locations, they may not be identical at all; one could be in a very hot climate with a flat surface, while the other could be a cold, snowy climate with a mountainous surface. Looking at a road map only gives you so much information about a location, and looking at the molecular identity of a substance will also only give you so much information about that substance. In either the chemical substance or road map scenario proposed above, increased granularity is required to perform a sufficient analysis.

2. Lack of Risk Assessment and Uncertainty of Risks

The legislative intent behind TSCA is to balance the risks posed by a product against the benefits and economic consequences of regulation, but it may be difficult to find balance when the risks posed by a product are unknown. It can be argued that the EPA has slowed the risk assessment process by not requiring manufacturer testing of nanoscale materials.[152]

TSCA Section 5 gives the EPA authority to require testing of new chemicals or significant new uses of existing chemical substances when there is believed to be an unreasonable risk.[153] This authority, however, does not mandate that the EPA must require testing, and it is no surprise that this power is used very conservatively due to limited resources and fear of political backlash.[154] Imposing burdensome material testing requirements could be viewed as being insensitive to those affected by the weak economy and could hamper the development of beneficial nanoscale products. If material testing was required before

151. Specifically, the EPA looks at whether two substances have (1) different molecular formulas, (2) the same molecular formula but different atom connectivities, (3) the same molecular formulas and atom connectivities but different spatial arrangement of atoms, or (4) the same types of atoms but different crystal lattices. The EPA also looks at whether the two substances are different allotropes of the same element, or different isotopes of the same element. *Id.* at 3–4.

152. *See* Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 699 (2007).

153. 15 U.S.C. § 2603(a) (2011).

154. Wagner, *supra* note 152, at 699.

nanotech products could be manufactured, there would be less incentive for development of nanotech products, as the testing would be an added cost to the manufacturers.

Manufacturers may also feel that there is an incentive *not* to generate risk assessment information.[155] TSCA generally considers a lack of information about a substance as indicating a lack of risk associated with that substance.[156] This gives manufacturers very little incentive to conduct in-depth risk assessment research, because there is no sanction for not undertaking that research and there may be penalties in the form of heavier regulation if they do provide data.

3. Applying the Least-Burdensome Regulations

The final issue in regulating nanotechnology through TSCA is the requirement that the EPA utilize the least burdensome alternative when applying regulations. Although TSCA gives the EPA comprehensive authority over any chemical substance or mixture, it has been noted that the "procedural and evidentiary demands of the statute sap it of much of its effectiveness."[157] That was evident in *Corrosion*, in which the Fifth Circuit demonstrated that what is "least burdensome" can be a very subjective determination.[158] The EPA had conducted ten years of research compiled into a 45,000-page record before acting to ban asbestos. The EPA felt its finding supported a regulation banning asbestos, but the court found the EPA's decision to be unduly burdensome.[159]

In *Corrosion*, the court found that by banning asbestos, the EPA had utilized the "most burdensome" of the possible alternatives for limiting production, stating that TSCA lists the seven alternatives in order of how burdensome they are.[160] However, while a complete ban on a product can intuitively be labeled as "most burdensome," the statute does not explicitly state that the alternatives are listed in a hierarchy from most burdensome to least.[161] The Fifth Circuit determined that this is meant to be a hierarchy, but the statute allows that the alternatives can be used in combination, implying that no hierarchy was intended.[162] This inconsistency can make it very difficult for the EPA to utilize the least burdensome regulation, because other than banning production

155. *See* DAVIES 3, *supra* note 96, at 11–12.

156. *Id.*

157. PERCIVAL ET AL., *supra* note 97, at 243.

158. *Id.* at 249.

159. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1215–17 (5th Cir. 1991).

160. *Id.*

161. 15 U.S.C. § 2605(a) (2006).

162. *Corrosion Proof Fittings*, 947 F.2d at 1217.

entirely, it is not clear which alternatives will be considered more burdensome than others.

Overall, regulating nanotechnology through TSCA will be difficult, at best. Some argue that TSCA is insufficient for regulating nanotechnology simply because it is a twentieth-century statute that was created at a time when nanotechnology was not even a consideration.[163] Classifying nanotech products through TSCA, balancing the risks and benefits, and applying the least burdensome regulations may create challenges for the EPA that will be difficult to overcome.

III. REGULATING NANOTECHNOLOGY

While the EPA and other regulatory agencies are under pressure to reduce EHS risks as human exposure to nanotechnology increases, there is also pressure to avoid over-regulating industries and companies that are creating new, useful technology and keeping the United States at the forefront of technological development. This is especially true at a time when the economy is unstable and regulatory burdens could be too costly for manufacturers to bear.

What is needed most at this point is *balance*. While TSCA was enacted to achieve balance, for the reasons stated above, it may not be sufficient for managing modern technologies with widespread applications, like nanotechnology.[164] The need for a more comprehensive nanotech oversight than TSCA can provide may be an opportunity to explore broader reform for the federal agencies that are already "suffer[ing] from under-funding and bureaucratic ossification" while trying to apply twentieth-century regulations to twenty-first-century technologies.[165] Applying minor rule changes and increasing budgets to implementing current statutes are not adequate measures for dealing with new technologies.[166] Instead, we should focus on new organizational forms within federal agencies.[167]

There have been many suggestions for new laws and new organizational forms for regulating nanotechnology. In this Section, I will explore three of those possibilities. One suggestion is to avoid federal regulations entirely and allow the nanotech industry to self-regulate.[168] Self-regulation of nanotechnology would utilize the knowledge and experience

163. *See* DAVIES 2, *supra* note 27, at 23-24.

164. *See supra* Part II.B.

165. DAVIES 2, *supra* note 27, at 3.

166. *See id.* at 24.

167. *Id.*

168. Diana M. Bowman & George Gilligan, *The Private Dimension in the Regulation of Nanotechnologies: Developments in the Industrial Chemicals Sector*, 28 UCLA J. ENVTL. L. & POL'Y 77, 77 (2010).

of experts within the industry, who would be responsible for creating a set of guidelines or a code of conduct for industry participants to adhere to.[169] Another recommendation is to create a new federal agency that would manage the EHS risks associated with chemicals or substances as well as the risks associated with products.[170] This recommendation would apply to nanotechnology as well as other modern technologies.[171] A third option would be to combine the efficiency of self-regulation with the oversight of a federal agency to create a form of co-regulation for addressing nanotechnology risks.[172] This could be accomplished by expanding key agencies to include "Nanotech Divisions" that would employ various processes to ensure a balanced approach to risk assessment and management.[173]

A. Self-Regulation

Self-regulation is not meant to exempt industry from complying with federal laws and regulations. It is meant to allow nongovernmental entities to independently create their own rules, codes of conduct and enforcement measures to implement existing government rules and regulations.[174] Self-regulation can occur at an individual level, where an entity would regulate itself, or a group level, where an industry or association would set rules and standards to be followed by all entities within that industry or association.[175]

The idea that governments should not monopolize regulation has been explored through discussions of decentering regulation.[176] The concept of decentering regulation posits that industries, organizations, and associations can and should have the power to regulate internally and that the role of government regulation should be limited as much as possible.[177] This suggests that there should be a shift away from total government regulation by allowing self-regulation because this would allow for greater flexibility in product development and less regulatory burden on smaller developers and manufacturers of certain products.[178]

169. *Id.* at 85–86.

170. *See* DAVIES 2, *supra* note 27, at 24.

171. *Id.*

172. *See infra* Part III.C.

173. *See infra* Part III.C.

174. Bowman & Gilligan, *supra* note 168, at 86.

175. Neil Gunningham & Joseph Rees, *Industry Self-Regulation: An Institutional Perspective*, 19 LAW & POL'Y 363, 364 (1997).

176. Julia Black, *Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a 'Post-Regulatory World'*, CURRENT LEGAL PROBLEMS: VOLUME 54 103, 103 (2001).

177. *Id.*

178. *Id.*

There are several potential benefits to self-regulation. It makes sense to allow industry practitioners and experts to be involved in the regulation process. Those experts can make decisions efficiently without the constraints of federal agency decision-making processes.[179] Self-regulation would also allow industries to bypass the legislative process in developing rules and procedures to ensure compliance with existing government regulations.

When an industry or association is self-regulated by those who are familiar with the intricacies of the industry, there is a higher level of expertise not often found among legislators.[180] Because self-regulation has flexibility, efficiency, and expertise, it promotes a regulatory atmosphere where a manufacturer will feel it is being governed by a code that applies to it directly—one that will conform to the manufacturers' changing needs, rather than a broad, general standard to which manufacturer must conform.[181]

B. Federal Agency Regulation

As discussed above, current federal statutes like TSCA are a poor fit for nanotechnology.[182] It is difficult to determine whether a nanoscale version of a material would be considered a "new" or "existing" material when the large-scale version is already on the TSCA inventory.[183] We have already seen that a nanoscale version of a substance can be significantly different from the large-scale version, but through TSCA, these markedly different substances will be treated as if they are the same.[184] It is also difficult to balance the risks and benefits of nanotechnology through TSCA, as nanotechnology is a widespread field with many applications. With these difficulties, the EPA may struggle to determine the least burdensome way to regulate nanotechnology.[185] Overall, TSCA creates a disincentive for manufacturers to generate or provide risk information for their chemicals and products because it is assumed that if there is no risk information, there is no risk.[186]

One commentator, J.C. Davies, has suggested that TSCA is simply too outdated and too weak for regulating nanotechnology and that merely making adjustments within TSCA will not fix these deficien-

179. Gunningham & Rees, *supra* note 175, at 366; Robert Heidt, *Industry Self-Regulation and the Useless Concept "Group Boycott"*, 39 VAND. L. REV. 1507, 1563 (1986).

180. Heidt, *supra* note 179, at 1562.

181. *Id.* at 1561–62.

182. *See supra* Part II.B.

183. *See supra* Part II.B.1

184. *See supra* Part II.B.1

185. *See* Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1229 (5th Cir. 1991).

186. DAVIES 3, *supra* note 96, at 11–12.

cies.[187] Davies is a senior project advisor to the Project on Emerging Nanotechnologies and one of the co-authors of the plan that created the EPA in the 1970's.[188] Davies recommends addressing nanotechnology by creating a new federal agency—the Department of Environmental and Consumer Protection (DECP).[189] The DECP would be tasked with more than just regulating nanotechnology and would be useful in addressing the challenges posed by twenty-first-century technological advances in general.[190]

This plan would work to address many issues that arise as we try to regulate modern technology through the existing agencies and regulations created to protect public health. The idea of integrating and restructuring the existing agencies to create an entirely new administrative framework is daunting, but we are at a time in technological development where it will become increasingly difficult to fix the shortcomings of the current regulatory scheme.[191]

Even if the proposed DECP seems extreme during this time of economic strain, its merits are worth exploring. Davies' proposal addresses many of the weaknesses in trying to apply the current environmental regulatory system to modern technology. For effective oversight, Davies argues that new concepts, types of organizations, and tools will be necessary.[192] The large-scale environmental problems created by nanotechnology (and other modern technologies) are not compatible with the current "fragmented system" of oversight.[193] This fragmented system is made up of legislation including the Clean Air Act, the Clean Water Act, and various waste disposal programs. Each program works individually, which is an inefficient way to manage areas of environmental concern because the seemingly different areas of the environment are all in reality interconnected.[194] In many cases, and especially when it comes to nanotechnology, regulating the risks associated with different products would benefit from combined risk research and monitoring.[195]

Creating the DECP would provide much-needed flexibility to the organizations responsible for regulating nanotechnology.[196] It would not

187. DAVIES 2, *supra* note 27, at 23–25.

188. *Id.* at 2.

189. *Id.* at 3.

190. *Id.* at 24.

191. *Id.*

192. *Id.*

193. *Id.*

194. *Id.* at 25.

195. *Id.*

196. *Id.*

eliminate and replace but would incorporate existing agencies.[197] The agencies to be incorporated would include: (1) the EPA; (2) the US Geological Survey; (3) the National Oceanic and Atmospheric Administration; (4) the Occupational Safety and Health Administration; (5) the National Institute of Occupational Safety and Health; and (6) the Consumer Products Safety Commission.[198] Through oversight, research, and monitoring, the proposed agency could also be used to address other complicated environmental issues, like climate change.[199] Incorporating the six agencies into the DECP would allow for a greater influence on policy and sufficient resources to address the new and ever-changing issues that accompany modern technology.[200]

C. Co-Regulation[201]

The benefits of self-regulation are appealing in a new, specialized field like nanotechnology because it allows those who are most familiar with the intricacies of the field to develop rules in a flexible and efficient manner. But even with these benefits, self-regulation is not the best route for managing the EHS risks of nanotechnology. There has been a certain level of discomfort expressed by the public and activist groups, who tend to believe that allowing industries and companies to self-regulate is akin to allowing those entities to not be regulated at all, and that self-regulation of nanotechnology will not sufficiently protect public health or the environment.[202] Additionally, the idea of self-regulation does not quite fit because nanotechnology is not an industry, but rather a technology that has infiltrated a variety of industries.[203] Self-regulation is propelled by the idea of an industry banding together with a common goal to promote product stewardship, but coordinating all of the nanotech industries would prove to be more difficult and there would be too many variances in values and industry norms for self-regulation to be effective.

Self-regulation has been put to use in the past through the chemical industry's Responsible Care Program (RCP).[204] Created in Canada in 1985, the RCP was adopted in the United States in 1989 to help increase

197. *Id.* at 26.

198. *Id.*

199. *Id.*

200. *See id.*

201. Also known as audited regulation or mandated, sanctioned or coerced self-regulation. *Id.*

202. *Id.*

203. DAVIES 1, *supra* note 19, at 29–30.

204. Andrew A. King & Michael J. Lenox, *Industry Self-Regulation Without Sanctions: The Chemical Industry's Responsible Care Program*, 43 ACAD. MGMT. J. 698, 698-99 (2000).

the public's confidence in chemical companies, and it is now part of a global initiative to improve environmental and health performance within the chemical industry.[205] The main focus of the RCP is to enhance product stewardship by improving risk communication through the supply chain.[206] More than fifty national chemical management associations participate in the program, which is managed globally by the International Council of Chemical Associations (ICCA).[207] National chemical associations commit to the program through an application process administered by the ICCA.[208] Once a national chemical association is part of the program, chemical companies within that nation may voluntarily enroll in the RCP, which is then implemented by the national chemical association in accordance with the goals and mission of the ICCA.[209]

There has been some debate over whether self-regulation is a sufficient means to achieve environmental and public health goals in the absence of heavy government regulation.[210] Some argue that without explicit sanctions in place to prevent opportunistic behavior, self-regulation will not succeed.[211] Others argue that explicit sanctions are not necessary for successful self-regulation because industry behavior will be controlled "through informal means of coercion, the transferal of norms, and the diffusion of best practices."[212] The RCP is an example of self-regulation that is not implemented through explicit sanctions.[213]

Another argument against self-regulation is that it seems to serve the industry being regulated instead of the public interest.[214] This has been viewed as "an attempt to deceive the public into believing in the responsibility of a[n] irresponsible industry" or "a strategy to give the government an excuse for not doing its job."[215] In 2005, two non-governmental entities, DuPont Chemical Company and Environmental

205. *Responsible Care*, INT'L COUNCIL OF CHEM. ASS'NS, http://www.icca-chem.org/en/Home/Responsible-care (last visited May 17, 2013).

206. *Id.*

207. *Id.*

208. *FAQs*, INT'L COUNCIL OF CHEM. ASS'NS, http://www.icca-chem.org/en/Home/Responsible-care/FAQs (last visited May 17, 2013).

209. *Id.*

210. *See* King & Lenox, *supra* note 204, at 698.

211. *Id.*

212. *Id.*

213. *Id.* at 700.

214. Gunningham & Rees, *supra* note 175, at 366.

215. *Id.* at 370 (quoting John Braithwaite, *Responsive Regulation for Australia*, *in* BUSINESS REGULATION AND AUSTRALIA'S FUTURE 81, 93 (Grabosky & Braithwaite eds., 1993).

Defense, joined together to create the Nano Risk Framework, a voluntary risk assessment framework for nanotechnology.[216] This attempt at jump-starting self-regulation was rejected by several activist groups who claimed that "[t]he history of other voluntary regulation proposals is bleak; voluntary regulations have often been used to delay or weaken rigorous regulation and should be seen as a tactic to delay needed regulation and forestall public involvement."[217]

Self-regulation may also be burdensome on the nanotech industry financially. Some would argue that self-regulation places minimal financial burden on industry, but without government oversight there will be no government funding to support the necessary research and risk assessments or the implementation and auditing of the rules that result from those assessments. This could place an especially heavy burden on the smaller sectors of the nanotech industry that may not have the resources to perform testing.

Federal agency regulation of nanotechnology has proven to be a complicated matter up to this point. Initial attempts to regulate nanotechnology through TSCA have been sloppy and difficult,[218] and past attempts by the EPA to regulate other potentially unsafe materials through TSCA have been rejected, even with large amounts of research supporting the EPA's position.[219]

Davies' idea of integrating federal agencies to create the DECP is intriguing, but may not be feasible. It is important not to hinder industry and new technology development with heavy regulatory burdens during a turbulent political climate and a struggling economy. Creating a new agency would be a large regulatory undertaking, and this could be viewed as a step towards heavier regulatory burdens on industry at a time when industry is already burdened by many other financial difficulties.

When it comes to nanotechnology, the number of industry experts is increasing every day, but the federal agencies are failing to keep up with the expanding field. With the current statutes in place, the EPA is not equipped to assess and manage the EHS risks of nanotechnology. Trying to regulate nanotechnology through TSCA is like trying to fit a square peg into a round hole—it just won't work.[220]

Co-regulation through the creation of new, interconnected divisions within key agencies will overcome the weaknesses of self-regulation and the difficulties of government regulation through TSCA or the creation

216. *Activist Groups Reject DuPont-ED Nanotechnology Risk Framework*, NANOWERK (Apr. 12, 2007), http://www.nanowerk.com/news/newsid=1766.php.

217. *Id.*

218. *See supra* Part II.B.

219. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1207 (5th Cir. 1991).

220. *See supra* Part II.B.

of the DECP. This co-regulation program would incorporate the expertise and flexibility of self-regulation with the oversight of a federal agency. I am proposing that each federal agency that will address nanotechnology be expanded to include a "Nanotech Division" (ND).

The NDs would work through a five-step process. First, the NDs will be created to employ industry and agency nanotech experts. Second, the NDs would begin gathering information from nanotech industry participants through a mandatory program. Third, the NDs would conduct thorough quantitative risk assessments based on the information gathered from industry participants. Fourth, the NDs would establish guidance documents or recommend regulations where necessary to address EHS risks. Finally, the NDs will be expanded or minimized as deemed necessary by the outcomes of the continuing risk research.

The final intensity of governmental regulatory authority over a nanotech product or nanosubstance will be dependent on the outcome of the risk assessments, with heavier government authority for a higher level of proven risk and lighter government authority for a lower level of proven risk. The complexity of heavier government authority will be justified if there is a high level of proven risk. Inversely, a low level of proven risk will show little need for government oversight and lighter government authority will be appropriate.

1. Step One: Creating Nanotech Divisions

The agencies that would expand or reorganize to include NDs would be the same agencies that Davies recommends for incorporation into the DECP: (1) the EPA; (2) the US Geological Survey; (3) the National Oceanic and Atmospheric Administration; (4) the Occupational Safety and Health Administration; (5) the National Institute of Occupational Safety and Health; and (6) the Consumer Products Safety Commission.[221] Throughout the five-step process, each ND would work with its parent agency to address the specific concerns of that agency and would also work cooperatively with other NDs as many of the potential risks and applicable assessments will overlap.

One initial concern will be the lack of government employees who are nanotech experts. In general, nanotechnology experts will earn more money working in the private sector than they would as a government employee. Budgeting is always an issue, and there simply may not be resources to pay more to employ experts within the existing agencies. This is one of the main justifications for utilizing co-regulation—government employees are not expected to have this type of expertise when it comes to nanotechnology. Instead of hiring nanotechnology experts as agency employees, each agency could set aside a portion of its budget to use towards working with industry experts on a contract basis, either to provide the agency with information as needed or to give the

221. DAVIES 2, *supra* note 27, at 26.

agency's ND employees training to help build their expertise in nanotechnology.

2. Step Two: Manufacturer Information Production

Once the NDs are created, they will begin gathering material information. The information-gathering process would follow the structure of a program implemented several years ago, but with some key changes. In 2005, the EPA National Pollution Prevention and Toxics Advisory Committee (NPPTAC) set forth a framework for a Nanoscale Materials Voluntary Program, which would later be called the Nanoscale Materials Stewardship Program (NMSP).[222] This framework included suggestions for a "basic" program and an "in-depth" program.[223] The basic program applies to *Step Two* of my recommendation, while the in-depth program would apply to *Step Three*. The basic program involved three activities for each nanoscale material:

> 1) Reporting existing . . . material characterization information on the material in commerce and materials soon to enter commerce, as well as existing information characterizing hazard, use and exposure potential, and risk management practices; 2) Filling in gaps in basic information about material characteristics ONLY; and 3) Implementing basic risk management practices.[224]

The EPA created the basic program in hopes of having a broad range of organizations participate in providing relevant information on material characterization, hazard information, use and exposure potential, and risk management practices.[225] As part of the program, the organizations would also agree to implement environmental and occupational safety controls such as hazard communication, worker training, and waste management practices.[226]

The basic flaw of the NMSP was that the voluntariness of the program invited low levels of participation. Between the start of the NMSP and the final information submission date on July 28, 2008, sixteen companies and trade associations voluntarily submitted

222. INTERIM AD HOC WORK GROUP ON NANOSCALE MATERIALS, EPA, OVERVIEW OF ISSUES FOR PUBLIC DISCUSSION AND CONSIDERATION BY NPPTAC 1 (2005), *available at* http://www.epa.gov/oppt/npptac/pubs/ nanowgoverviewdraft 050921finalv2.pdf [hereinafter NNPTAC]; *see generally Concept Paper for the Nanoscale Materials Stewardship Program Under TSCA*, EPA (Jan. 21, 2010), http://www.epa.gov/oppt/nano/nmsp-conceptpaper.pdf.

223. NPPTAC, *supra* note 222, at 4.

224. *Id.*

225. *Id.* at 5.

226. *Id.*

information on ninety-one nanoscale materials for the basic program.[227] The information gathered through the basic program included very basic chemical and manufacturing information, but very few submissions actually included toxicity information as the submitters considered this information to be confidential business information.[228] The EPA stated that "approximately 90% of the different nanoscale materials that are likely to be commercially available were not reported under the Basic Program,"[229] so the information gathered during the basic program represents a small fraction of nanotechnology.

A way to overcome this flaw as the NDs make another attempt to gather information from manufacturers would be to utilize different methods to encourage participation. One method could be requiring mandatory participation. Participation could be required without placing a heavy burden on manufacturers because *Step Two* of the program would simply be gathering the information manufacturers already have on hand, even if this information is minimal. The information gathered would be protected as confidential business information and would be used generally to assess EHS risks. Manufacturers that fail to participate in a mandatory disclosure of information could be fined to help fund the other ND program steps.

If mandatory participation would be considered too burdensome, the ND could still encourage voluntary participation using economic tools. For example, if a manufacturer willingly provides product information for this step, that manufacturer would benefit from not having to test those materials because the ND would perform testing during *Step Three* risk assessment. Manufacturers that do not willingly provide their basic product information during *Step Two* could be required to perform the risk assessments from *Step Three* at their own expense.

3. Step Three: Quantitative Risk Assessments

Step Three would involve quantitative risk assessments similar to those from the in-depth program of the NMSP. The in-depth program was designed to go beyond the basic program by taking the information provided through the basic program and generating new, in-depth information about the nanotech materials.[230] The in-depth information

227. OFFICE OF POLLUTION PREVENTION & TOXICS, EPA, NANOSCALE MATERIALS STEWARDSHIP PROGRAM INTERIM REPORT 3 (2009), *available at* http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf.

228. *Id.* at 9. Confidential business information may be submitted through the NMSP, but this information is protected under 15 U.S.C. Section 2613 and 40 CFR Parts 2 and 720 and is therefore not subject to public disclosure. *Id.*

229. *Id.* at 27.

230. NPPTAC, *supra* note 222, at 6.

would be obtained through monitoring workplaces, environmental releases and worker health, and quantitative risk assessments.[231]

For a more thorough assessment than was provided by the NMSP, the NDs quantitative risk assessments would be accomplished through the US government's National Nanotechnology Initiative (NNI). The NNI was launched as a collaborative agency effort in 2001.[232] The goals of the NNI are (1) "[t]o advance world-class nanotechnology research and development"; (2) "[t]o foster the transfer of new technologies into products for commercial and public benefit"; (3) "[t]o develop and sustain educational resources, a skilled workforce and the supporting infrastructure and tools to advance nanotechnology"; and (4) "[t]o support the responsible development of nanotechnology."[233] While researching EHS risks associated with nanotechnology is an essential step towards achieving each of these goals, it is most closely related to the goal of "responsible development."[234]

The NNI was created to allow all of the agencies that may be involved with nanotechnology to work together with the nanotech industry to conduct research in the field, but the NNI is a general research initiative that focuses more on development of nanotech products than researching nanotech risks. There is some federal funding for NNI through the 21st Century Nanotechnology Research and Development Act of 2003 (NRD Act),[235] but only 3 to 4 percent of federal NNI funding is used

231. *Id.*

232. NAT'L SCI. & TECH. COUNCIL COMM. ON TECH. SUBCOMM. ON NANOSCALE SCI., ENG'G, & TECH., NAT'L NANOTECH. INITIATIVE, STRATEGIC PLAN 1 (2011), *available at* http://nano.gov/sites/default/files/pub_resource/2011_strategic_plan.pdf.

233. *NNI Vision, Goals, and Objectives*, NAT'L NANOTECHNOLOGY INITIATIVE, http://www.nano.gov/about-nni/what/vision-goals (last visited May 13, 2013).

234. NATIONAL NANOTECHNOLOGY INITIATIVE, 2011 ENVIRONMENTAL, HEALTH, & SAFETY STRATEGY 1 (2010), *available at* http://www.nano.gov/sites/default/files/pub_resource/draftehsstrategy-17dec2010-to_post.pdf [hereinafter STRATEGY].

235. 21st Century Nanotechnology Research and Development Act, 15 U.S.C. § 7501 (2005).

towards risk assessment research.[236] Additional risk assessment funding comes from the federal agencies themselves.[237]

The risk assessment process outlined by the NNI follows a basic scientific procedure that includes identifying hazards, assessing magnitude of exposure, assessing dose-response relationships, and characterizing risks.[238] This process is generally accepted within the scientific and regulatory communities because it creates perspective between toxicity, hazards, and risks associated with a material.[239]

4. Step Four: Developing Guidance and Regulations

Step Four of my recommendation is for the NDs to use the gathered risk information to develop industry guidance documents or to recommend new regulations as necessary. This is a step that will occur at regular intervals simultaneously with the other steps. The information gathered in *Step Two* and the research conducted in *Step Three* will give some indication as to the EHS risks presented by nanotechnology. Minimal or uncertain risks can be addressed through guidance documents, while serious risks can be addressed through regulations.

Industry guidance for nanotechnology has been difficult to establish. One reason for this is the fact that there is still so much uncertainty as to the EHS risks of nanotechnology. Because the risks are uncertain, it is difficult to guide industry on avoiding those risks, but there should still be some form of guidance, even if minimal at first, to assist manufacturers of nanoproducts in making decisions about how to handle those products. For example, the National Institute for Occupational Safety and Health has created a guidance document called *Approaches to Safe Nanotechnology* to assist manufacturers in implementing occupational safety measures to help reduce worker exposure to nanoparticles.[240] The

236. *National Nanotechnology Initiative Needs Fundamental Restructuring to Effectively Address Nano Risks: Conflict Between Promotion, Oversight Roles Impedes Balanced Approach*, ENVIRONMENTAL DEFENSE FUND (Oct. 31, 2007), http://www.edf.org/news/national-nanotechnology-initiative-needs-fundamental-restructuring-effectively-address-nano-ris. Even the 3–4 percent figure is questioned because an unknown amount of funds are used towards researching the development of nanotech products "where it deems the research to be 'relevant' to answer risk questions." *Id.*

237. *NNI Budget*, NAT'L NANOTECHNOLOGY INITIATIVE, http://nano.gov/about-nni/what/funding (last visited May 15, 2013).

238. STRATEGY, *supra* note 234, at 2.

239. MARY K. THEODORE & LOUIS THEODORE, INTRODUCTION TO ENVIRONMENTAL MANAGEMENT 407 (2010).

240. *See generally* NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, CTRS. FOR DISEASE CONTROL & PREVENTION, NIOSH 2009-125, APPROACHES TO SAFE NANOTECHNOLOGY: MANAGING THE HEALTH AND SAFETY CONCERNS ASSOCIATED WITH ENGINEERED NANOMATERIALS (2009), *available at* http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf.

occupational health and safety risks associated with nanotechnology are also uncertain at this time, but this guidance was created to address the *potential* concerns as a safeguard while thorough risk assessments are being performed.[241] Similar guidance could be created to address the potential risks.

The NNI Environmental, Health, and Safety Research Strategy was developed as guidance for agencies associated with nanomaterials to assist those agencies in understanding their responsibilities, to identify opportunities for agency collaboration, and to assist the NNI in achieving federal goals for nanotech health and safety.[242] This could be a good starting point for creating industry guidance through the NDs.

Regulations can be used to address significant risks. It is difficult to predict how the regulation process will occur because it is currently uncertain whether there are significant risks and what those risks may be. Once the risks are certain, each federal agency can determine whether those risks can be addressed through current regulations or whether new regulations need to be enacted. Creating new regulations is not a simple process, and that is why this option would be reserved for addressing known substantial risks discovered after the thorough risk assessment process of *Step Four*. Should this be necessary, the co-regulation would lean a bit more heavily towards government regulation.

5. Step Five: Adjusting Nanotech Divisions to Address Actual Risks

Step Five cannot be outlined in detail until the EHS risk research outcomes are determined. The purpose of this five-step process is to allow the regulation of nanotechnology to conform to the level of certain risk. The NDs will be created to address unknown risks and to promote researching those potential risks. As the research continues, there may be several potential outcomes. Nanotechnology may not present any EHS risks and may be deemed categorically safe. On the other hand, nanotechnology may be found to present a wide variety of serious risks and may be deemed categorically unsafe. A third (and likely) outcome falls between these two extremes—there may be some products and uses for nanotechnology that pose severe EHS risks while other products and uses pose no risks at all.[243] Whichever of these three outcomes occurs will determine whether the final regulatory structure will lean more towards self-regulation, government regulation, or a balanced co-regulation.

If nanotechnology is found to be categorically safe, the NDs can be reduced to smaller groups that can be used to continue testing and analyzing new products as they are created. The smaller NDs will have experience in analyzing the safety of nanotech products at that point and should be able to continue monitoring new products in an efficient

241. *See id.* at v–vi.

242. STRATEGY, *supra* note 234, at 1–2.

243. DAVIES 1, *supra* note 19, at 20.

yet thorough manner to ensure that the continued manipulation of nanoparticles does not create EHS risks in the future.

If nanotechnology is found to be categorically unsafe, the NDs may be used to create and enforce new federal regulations. The complex and lengthy process of creating new regulations would be appropriate at that point because there would be a need to protect the environment and the public from the proven risks associated with nanotechnology. The need for heavier government regulations may motivate certain manufacturers to abandon the risky nanotech products and either go back to using other existing products or develop a new, safer alternative to nanotechnology.

The most likely outcome from *Steps One* through *Four* is that nanotechnology will include a combination of products that create a very low level of risk, products that create a high level of risk, and some products that fall in between. Nanotechnology involves the manipulation of nature to such a degree that it is a logical assumption that there will be some risks. With this mixed outcome, the NDs can be adjusted within each agency to account for different regulatory needs.

For example, there may be a higher level of risk for employees who work directly with nanoparticles on a daily basis. These employees may have a higher likelihood of exposure to free nanoparticles in the air and on surfaces around them. The Occupational Safety and Health Administration could expand the role of its ND as necessary to account for the higher level of risk associated with worker exposure. At the same time, the EPA may find that there is actually very little risk associated with disposal of products that contain fixed nanoparticles—like sheets of metal with nanoscale components. With little risk at the time of disposal, the EPA's ND could minimize its focus on waste products containing nanoparticles and expand its efforts towards other areas where the level of risk is higher. This flexibility would allow each agency's ND to focus on the areas of higher risk with greater regulation and oversight. The nanotech industry would benefit by not having to face the burden of complying with regulations imposed on products that pose no risk, and the federal agencies would benefit by being able to focus efforts solely on areas of concern.

Overall, the Nanotech Divisions I am recommending will address some of the concerns presented by other nanotech programs by creating a flexible Five-Step program that can be adjusted based on the outcomes of ongoing EHS risk assessments. The program will be strict because it will include mandatory components requiring contributions from industry and mandatory guidance or regulations where necessary, but it will also be flexible by avoiding excessive regulation of unknown risks. This program will combine elements of self-regulation with a new federal agency structure that is able to address modern technologies.

Conclusion

Any program used to regulate nanotechnology must balance its benefits and uncertain risks. The EPA has addressed new technologies and unknown risks in the past but may not be equipped to address the uncertainties posed by nanotechnology. Through a program that addresses the gaps in current TSCA regulation and allows for utilization of industry expertise, proper risk assessments can be conducted to ensure that technological advances presented by nanotechnology are both beneficial and safe. My recommendation for co-regulation through the creation of a Nanotech Division within the EPA and other agencies addresses the weaknesses associated with trying to regulate nanotechnology through TSCA by incorporating components from existing programs, with some adjustments, to create a more comprehensive program that is well-suited for regulating nanotechnology. This co-regulation will address the current unknown EHS risks of nanotechnology and will prepare the EPA and other agencies for long-term regulation of nanotechnology once the EHS risks have been established.